

Official IR
12 May 98

BD1 CIP FWC IV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Sherie L. Morrison et al.
Serial No. : 08/266,154
Filed : June 27, 1994
For : METHODS FOR PRODUCING FUNCTIONAL
IMMUNOGLOBULIN, INCLUDING CHIMERIC
IMMUNOGLOBULIN, IN TRANSFORMED
MAMMALIAN LYMPHOCYTIC CELLS
Group Art Unit : 1806
Examiner : Julie E. Reeves, Ph.D.

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

May 11, 1998

REVISED AMENDMENT AFTER ALLOWANCE
PURSUANT TO 37 C.F.R. 1.312(a)

Sir:

Applicants request approval under Rule 312(a) for entry of the following amendment without withdrawing the case from issue.

IN THE CLAIMS

Please add the following claims 126-137.

P

ok to enter
IR
12 May 98

31 126. A method for producing a functional antigen-binding protein

comprising

- i) a first chain comprising an immunoglobulin heavy chain variable domain and an immunoglobulin heavy chain constant domain and
- ii) a second chain comprising an immunoglobulin light chain variable domain and an immunoglobulin light chain constant domain,

wherein the method comprises the steps of:

- (a) transfecting a transformed mammalian lymphocytic cell with a first DNA molecule coding for the first chain of the protein;
- (b) transfecting the cell with a second DNA molecule, said second DNA molecule coding for the second chain of the protein; and
- (c) maintaining the cell in a nutrient medium, so that the cell expresses the first and second DNA molecules and the resultant chains are intracellularly assembled together to form the protein which is then secreted in a form capable of specifically binding to antigen

wherein prior to step (a) the cell does not express a functional antigen-binding protein.

32 127. A method as recited in claim 31 126 wherein prior to step (a) the cell does not endogenously produce any immunoglobulin chains.

33 128. A method as recited in claim 31 126 wherein prior to step (a) the cell endogenously produces an immunoglobulin light chain or an immunoglobulin heavy chain, but not both.

129. A method as recited in claim 126 wherein each chain comprises a constant region.

P. cont
Sub Q3

130. A method as recited in claim 126 wherein the variable domain is found in a first mammalian species and the constant domain is found in a second mammalian species, said second mammalian species being other than the first mammalian species.

131. A method as recited in claim 129 wherein the variable domain is found in a first mammalian species and the constant region is found in a second mammalian species, said second mammalian species being other than the first mammalian species.

37
132. A method for producing a functional antigen-binding protein comprising

- 10290149400
056151 052701
- i) a first chain comprising an immunoglobulin heavy chain variable domain and an immunoglobulin heavy chain constant domain and
 - ii) a second chain comprising an immunoglobulin light chain variable domain and an immunoglobulin light chain constant domain,

wherein the method comprises the steps of:

- (a) transfecting a transformed mammalian lymphocytic cell with a plasmid comprising a first DNA molecule coding for the first chain of the protein and a second DNA molecule coding for the second chain of the protein; and
- (b) maintaining the cell in a nutrient medium so that the cell expresses said first DNA molecule and said second DNA molecule and the resultant chains are intracellularly assembled together to form the protein which is then secreted in a form capable of specifically binding to antigen

wherein prior to step (a) the cell does not express a functional immunoglobulin capable of specifically binding antigen.

³⁸ 133. A method as recited in claim ³² 132 wherein prior to step (a) the cell does not endogenously produce any immunoglobulin chains.

134. A method as recited in claim 132 wherein prior to step (a) the cell endogenously produces an immunoglobulin light chain or an immunoglobulin heavy chain, which endogenously-produced heavy chain is not secreted in a form capable of specifically binding to antigen, but not both.

135. A method as recited in claim 132 wherein each chain has a constant region.

136. A method as recited in claim 132 wherein the immunoglobulin comprises the variable domain found in a first mammalian species and comprises the constant domain found in a second mammalian species, said second mammalian species being other than the first mammalian species.

137. A method as recited in claim 135 wherein the immunoglobulin comprises the variable domain found in a first mammalian species and comprises the constant region found in a second mammalian species, said second mammalian species being other than the first mammalian species.

REMARKS

Because claims 126-135 presented in applicants' prior § 312(a) amendment were not entered due to an indefiniteness rejection based on the language "derived from", applicants submit revised claims 126-137 for consideration by the

REV. 10/97
For Other Than A Small Entity

Docket No. BD1 CIP FWC IV

Applicant(s) : Sherie L. Morrison et al.
Serial No. : 08/266,154
Filed : June 27, 1994
For : METHODS FOR PRODUCING FUNCTIONAL
IMMUNOGLOBULIN, INCLUDING CHIMERIC
IMMUNOGLOBULIN, IN TRANSFORMED
MAMMALIAN LYMPHOCYTIC CELLS
Group Art Unit : 1806
Examiner : Julie E. Reeves, Ph.D.

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

May 18, 1998

TRANSMITTAL LETTER

Sir:

Transmitted herewith: ☐ a Preliminary Amendment;
☒ an Amendment under 37 C.F.R. § 1.312(a); ☒
Authorization to Charge Deposit Account; ☐ a substitute
Specification; ☐ a Declaration; ☐ a Supplemental
Declaration; ☐ a Power of Attorney; ☐ an Associate Power
of Attorney; ☐ formal drawings; to be filed in the above-
identified patent application.

FEE FOR ADDITIONAL CLAIMS

☐ A fee for additional claims is not required.

[X] A fee for additional claims is required.

The additional fee has been calculated as shown below:

| | CLAIMS REMAINING AFTER AMENDMENT | | HIGHEST NUMBER PREVIOUSLY PAID FOR | | PRESENT EXTRA | | RATE | | ADDITIONAL FEES |
|---|---|---|---|----|------------------|---|-------|---------|--------------------|
| TOTAL CLAIMS | 62 | - | 48 | * | = 14 | X | \$22 | = | \$308.00 |
| INDEPENDENT CLAIMS | 9 | - | 6 | ** | = 3 | X | \$82 | = | \$246.00 |
| FIRST PRESENTATION OF A MULTIPLE DEPENDENT CLAIM | | | | | | | | + \$270 | = \$ |
| * | If less than 20, insert 20. | | | | | | TOTAL | | <u>\$554.00</u> |

** If less than 3, insert 3.

[] A check in the amount of \$_____ in payment of the filing fee is transmitted herewith.

[X] The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. § 1.16, in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

[X] Please charge \$554.00 to Deposit Account No. 06-1075 in payment of the filing fee. A duplicate copy of this transmittal letter is transmitted herewith.

EXTENSION FEE

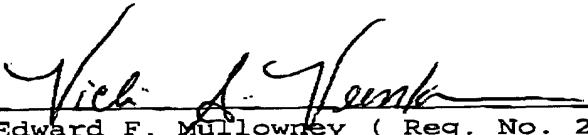
[] The following extension is applicable to the Response filed herewith; [] \$110.00 extension fee for response within first month pursuant to 37 C.F.R. § 1.17(a);

☐ \$400.00 extension fee for response within second month pursuant to 37 C.F.R. § 1.17(b); ☐ \$950.00 extension fee for response within third month pursuant to 37 C.F.R. § 1.17(c); ☐ \$1,510.00 extension fee for response within fourth month pursuant to 37 C.F.R. § 1.17(d).

☐ A check in the amount of ☐ \$110.00; ☐ \$400.00; ☐ \$950.00; ☐ \$1,510.00; in payment of the extension fee is transmitted herewith.

☒ The Commissioner is hereby authorized to charge payment of any additional fees required under 37 C.F.R. § 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

☐ Please charge the ☐ \$110.00; ☐ \$400.00; ☐ \$950.00; ☐ \$1,510.00; extension fee to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.


Edward F. Mallowney (Reg. No. 27,459)
Vicki S. Veenker (Reg. No. 34,269)
Attorneys for Applicants

c/o FISH & NEAVE
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000

00266154 052794

PATENTS

Applicant : Sherie L. Morrison et al.
Serial No. : 08/266,154
Filed : June 27, 1994
For : METHODS FOR PRODUCING FUNCTIONAL
IMMUNOGLOBULIN, INCLUDING CHIMERIC
IMMUNOGLOBULIN, IN TRANSFORMED
MAMMALIAN LYMPHOCYTIC CELLS
Group Art Unit : 1806
Examiner : Julie E. Reeves, Ph.D.

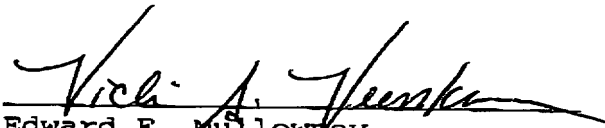
Hon. Assistant Commissioner for Patents
Washington, D.C. 20231

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

Sir:

The undersigned attorney hereby authorizes the Commissioner to charge the fee of \$554.00, or to credit any overpayment of same, due in connection with the Second Amendment after Allowance Pursuant to 37 C.F.R. 1.312(a) filed herewith to Deposit Account No. 06-1075.

A duplicate copy of this authorization is
transmitted herewith.


Edward F. Mallowkey
Registration No. 27,459
Vicki S. Veenker
Registration No. 34,269
Attorneys for Applicants

c/o FISH & NEAVE
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000

11/12/98 12:49:00